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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,587	09/06/2001	Antonio Grillo-Lopez	27693-01186	5272

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
12/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/762,587	GRILLO-LOPEZ, ANTONIO	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/03/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 7 is being examined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 remains rejected under 35 USC 103, as being obvious over Maloney et al, in view of Press et al, Kaminsky et al, 1996, and Kaminsky et al (US 6,287,537, filed 05/29/1998), and further in view of Wahl et al, for reasons already of record in paper of 04/09/07.

The response asserts that Kaminski '537 does not, as the Office suggests, describe any patients who are refractory to treatment with an unlabeled anti-CD20 antibody. The response asserts that the sentence on col. 21, lines 40-54, as cited by the Examiner, appears in a paragraph that begins, "The antibody moiety of the 131-I-B 1 conjugate may also be partly responsible for antitumor effects." The response asserts that the entire paragraph relates to evidence that the B 1 antibody per se exhibits antitumor activity. The response asserts that the fact that some patients may have exhibited a slower response to the B 1 antibody, as Kaminski '537 teaches, does not

contradict the central teaching of the paragraph, namely, that the B 1 antibody does contribute to the therapeutic response obtained with the combination B 1 + 131-I-B 1 therapy. The response asserts that it is not reasonable to cite a single sentence, removed from the context of the paragraph in which it appears, as teaching exactly the opposite of the point that the paragraph discusses. The response asserts that the Office's second point is that "the non-radiolabeled anti-CD20 antibody has some anti-tumor effect, [but] it is not efficient .... " The response asserts that if the antibody has "some antitumor effect" in a population of patients, those patients - by definition - are not refractory to the antibody. The response asserts that it does not matter that the antibody is "not efficient." The response asserts that this teaching refutes the position that the Office wishes to take.

The response has been considered but is not found to be persuasive for the following reasons:

It is noted that the treatment of lymphoma patients taught by Kaminski '537 comprises first **pretreatment with unlabeled anti-CD20 antibody**, followed by treatment with I-131 labeled anti-CD20 antibody (or RIT, radioimmunotherapy) (Examples 1-2 on columns 13-22, especially columns 14, 22).

The first part of the cited paragraph, column 21, lines 30-47, discusses that although the B 1 antibody per se exhibits some antitumor activity, this discussion is followed by the discussion, starting at line 48, that **however** a targeted radiation by I-131 labeled anti-CD20 antibody is effective in those cases that the response to the therapy is seen only after a large dose of unlabeled antibody, and in those cases in which a response occurs only after an RIT dose. Kaminski '537 teaching that "in those cases in which a response to the therapy occur **only after**

an RIT dose" (column 21, lines 48-49) clearly indicates that in those cases the patients do not response to the pretreatment with non-labeled anti-CD20 antibody, and only response after an RIT dose of I-131 labeled anti-CD20 antibody, in view that the treatment of lymphoma patients taught by Kaminski '537 comprises first pretreatment with unlabeled anti-CD20 antibody, followed by treatment with I-131 labeled anti-CD20 antibody.

Obvious-type Double Patenting

Claim 7 of the instant application remains provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9, 33, 42, 44-45, 47-48 of the copending US application SN= 10/196732, as evidenced by Maloney DG et al, 1997, Blood, 90(6): 2188-95, of record, for reasons already of record in paper of 04/09/07.

The response asserts as follows:

Neither this application nor the '732 application is allowed. Thus, applicant expects that if the copending application is not allowed and the double patenting rejection is the only rejection remaining, this application will be passed to issue in accord with the practice set forth at MPEP § 804, subsection I.B. Applicant notes that the cited claims of the '732 application are currently withdrawn as directed to nonelected inventions. Should the '732 application be allowed first, and provided that the claims in this application and in the '732 application are substantially the same as the cited claims now pending, without conceding the merits of the rejection, applicant agrees to file a terminal disclaimer in this application over any patent issuing on the '732 application.

Rejection remains, because claims 7-9, 33, 42, 44-45, 47-48 of copending application SN= 10/196732 are not cancelled, and no terminal disclaimer has been provided.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
November 27, 2007

/Larry R. Helms/
Supervisory Patent Examiner